CLAIMS

1. A method of detecting the presence in a sample of a polypeptide exogenously administered to a mammalian subject from whom the sample is obtained, and distinguishing between such an exogenously administered polypeptide and a naturally-occurring endogenous polypeptide present in the sample; the method comprising obtaining a sample from the subject; and subjecting the sample to analysis of fluorescence at a suitable wavelength; wherein the exogenously administered polypeptide is tagged with a greater or lesser amount of fluorescence activity, relative to the untagged endogenous polypeptide, at the wavelength(s) analysed.

2. A method according to claim 1, wherein the sample is subjected to processing, prior to fluorescence analysis, to enrich or purify the exogenous and endogenous molecules in the sample.

3. A method according to claim 1 ~~or 2~~, wherein the sample is subjected to processing, prior to analysis, by one or more of the following: centrifugation; HPLC; FPLC; affinity chromatography; immunoaffinity chromatography; denaturation or heat treatment.

4. A method according to ~~any one of claims 1, 2 or 3~~ claim 1, wherein the sample is a sample of body fluid or tissue obtained from a human or other mammalian subject.

5. A method according to ~~any one of the preceding claims~~ claim 1, wherein the sample comprises one or more of the following: blood; saliva; sweat; urine; semen; tears.

6. A method according to ~~any one of the preceding claims,~~ claim 1 wherein the tagged molecule has greater fluorescence activity, at the wavelength analysed, than the untagged molecule.

7. A method according to ~~any one of the preceding claims~~ claim 1, wherein the tagged molecule comprises one or more fluorophores not present in the untagged molecule.

8. A method according to claim 7, wherein a compound comprising a tagging fluorophore is incorporated in the tagged molecule by means of a peptide bond.

9. A method according to claim 7 ~~or 8~~, wherein the fluorophore comprises tyrosine, tryptophan or a synthetic amino acid derivative.

10. A method according to ~~any one of the preceding claims~~ claim 1, wherein the tagged molecule comprises a tagged therapeutic polypeptide and/or tagged hormone.

11. A method according to ~~any one of the preceding claims~~ claim 1, wherein the tagged molecule comprises one of the following: a tagged human, bovine or porcine growth hormone; tagged calcitonin; tagged erythropoietin; tagged growth hormone releasing factor; tagged insulin; or tagged interleukin-2.

12. A method according to ~~any one of the preceding claims~~ claim 1, wherein the tagged molecule comprises growth hormone tagged with a tryptophan residue at one or more of positions 10, 31, 97, 160 or 176.

13. A composition for administration to a mammalian subject, the composition comprising a polypeptide and a physiologically acceptable carrier substance, characterised in that the polypeptide is tagged with a greater or lesser amount of fluorescent activity relative to an untagged polypeptide endogenously present in the subject, the tagged molecule thereby being distinguishable from the untagged molecule by analysis of the fluorescence characteristics of the respective molecules, excluding those compositions in which the tagged molecule is Growth Hormone and wherein the fluorescent tagging consists solely of one or more of the following substitutions in the tagged Growth Hormone: G40 → Y; F52 → Y; W86 → F, Y, L, I or V; F103 → Y; and I137 → Y.

14. A composition according to claim 13, wherein the tagged molecule comprises a number of tryptophan residues different from the number of tryptophan residues present in the untagged molecule, and the tagging is effected thereby.

15. A composition according to claim 13 ~~or 14~~, wherein the tagged molecule comprises two or more tryptophan residues greater than the number of tryptophan residues present in the untagged molecule.

16. A composition according to ~~any one of claims 13, 14 or 15~~ claim 13, wherein the tagged molecule comprises a therapeutic polypeptide and/or hormone.

17. A composition according to ~~any one of claims 13-16~~ claim 13, wherein the tagged molecule comprises one of the following: tagged human, bovine or porcine growth hormone; tagged

calcitonin; tagged erythropoietin; tagged growth hormone releasing factor; tagged insulin; or tagged interleukin-2.

18. A composition according to ~~any one of claims 13-17~~ claim 13, wherein the tagged molecule comprises growth hormone tagged with a tryptophan residue at one or more of positions 10, 31, 97, 160 or 176.

19. A tagged growth hormone comprising a tryptophan residue substituted for a phenylalanine residue present in a naturally-occurring growth hormone molecule.

20. A tagged growth hormone comprising a tryptophan residue at one or more of positions 10, 31, 97, 160 or 176.

21. A tagged growth hormone comprising a tryptophan residue at position 31 and/or 97.

22. A nucleic acid sequence encoding a tagged growth hormone in accordance with ~~any one of claims 19, or 21.~~ claim 19

23. A nucleic acid expression construct comprising a nucleic acid sequence in accordance with claim 22.

24. A nucleic acid sequence comprising nucleotides 114-695 of the nucleic acid sequence shown in Figure 2.

25. A method substantially as hereinbefore defined.

26. A composition substantially as hereinbefore defined.

Add C3